IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
DANVILLE DIVISION

LOIS LORRAINE ADKINS	)	
	)	
Plaintiff,	)	
v.	)	
CYTYC CORPORATION, *et al.*,	)	
	)	Case No. 4:07cv00053
Defendants.	)	

MEMORANDUM OF LAW IN REPLY TO PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS

After plaintiff filed its complaint in this case, the United States Supreme Court in *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008), held that the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") preempt state common law claims implicating the design, manufacturing process, and labeling of a Premarket Approved medical device such as the NovaSure Endometrial Ablation System, the device at issue in this case.

Plaintiff acknowledges that "[f]ollowing *Riegel*, "her claims of breach of implied warranty, breach of express warranty and negligence, to the extent they fault the design, manufacturing and labeling of the NovaSure device" "are likely preempted by the MDA." Plaintiff's Response at 7 (April 21, 2008) (Docket # 32). Plaintiff argues, instead, that *Riegel* is not applicable to the statements made by Cytyc's corporate representative because those statements "are not directed to the safety and effectiveness of the NovaSure device . . . ." *Id.* at 8. According to plaintiff, the corporate representative "had a duty to ensure that the NovaSure

device was operating correctly and that Dr. Ensminger (the surgeon, treating physician) followed the proper procedures when using the device." Complaint at ¶ 31.

There are three problems with plaintiff's argument. First, if the corporate representative's statements do not relate to safety and effectiveness, then there can be no proximate causation between those statements and any injury that is alleged to have occurred. Second, the notion that a corporate representative owes a duty to instruct a treating physician on the proper use of a class III device is inconsistent with the FDA's conditions of approval and is therefore, preempted by the MDA. Finally, under Virginia law and the law of this Circuit, a device manufacturer's corporate representative owes no duty of care to a patient; that duty is owed by the physician under Virginia's learned intermediary doctrine. Absent a duty, there can be no negligence. "Proof of negligence in the air, so to speak, will not do." *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 341 (1928) (citations omitted).

1. Plaintiff's Concession that the Representative's Statements Did Not Involve the Device's Safety or Effectiveness Negates Negligence and Causation

It is by now axiomatic that to establish negligence, in addition to showing the existence of duty, a plaintiff must also show that some action or inaction on the defendant's part unreasonably increased the risk of injury and that action or inaction proximately caused injury. Reasonableness is measured by balancing the cost of prevention and the risk of injury. *See United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947)(defining negligence as the unreasonable balancing of the cost of safety measures against the risk of accidents).

Common law negligence is inherently intertwined with safety. Negligence is conduct "which falls below the standard established by law for the protection of others against unreasonable risk of harm." RESTATEMENT (SECOND) OF TORTS § 282 (1965). As a matter of

tort law, common sense, and the FDCA, the greater the risk of harm the greater the safety measures that ought to be taken. It is difficult of conceive of any definition of "risk of harm" involving bodily injury that does not relate to "safety." *See* 21 C.F.R. § 814.20(b)(3)(vi) (requiring a manufacturer to discuss the risks of its device as part of its Premarket Approval application demonstrating safety and effectiveness). The FDA classifies medical devices based on their risk profile. *See* Food, Drug, and Cosmetic Act § 513(a), 21 U.S.C. § 360c(a).

Therefore, if, as plaintiff alleges, the statements of the corporate representative to the surgeon did not relate to either "the safety or effectiveness" of the medical device, then those statements, by definition, could have had no effect on the patient's safety and as such, cannot form the basis of plaintiff's negligence claim. Indeed, it is difficult to understand the nature of plaintiff's negligence allegation against Cytyc's corporate representative when the complaint itself affirmatively acknowledged that the "corporate representative . . . directed Dr. Ensminger on the proper way to use the NovaSure device to measure the size of the plaintiff's uterus and to test the integrity of the uterine wall." Complaint at ¶ 15 (emphasis supplied).

2. A Corporate Representative Owes No Duty to a Patient to Instruct or Tutor a Physician

The basis of negligence is the existence of duty owed by the defendant to the plaintiff. *See Blue Ridge Serv. Corp. v. Saxon Shoes*, 271 Va. 206, 218 (2006). Plaintiff alleges that Cytyc's corporate representative owed her a duty "to ensure that the NovaSure device was operating correctly and that Dr. Ensminger followed the proper procedures when using the NovaSure device." Complaint at ¶ 31. No such duty is owed as a matter of federal law and therefore, any attempt to infer a contrary state standard would be preempted. Specifically, when the FDA approves a medical device, it not only approves the design, manufacturing, and labeling

of the device, but also may impose as a condition of approval various requirements on the sale or use of the device. *See* FDCA § 520(e) (The Secretary may impose "such other conditions" on the sale of the device as he deems appropriate). Thus, some devices and drugs are approved on the condition that they only be used in a hospital setting and others may be approved on the condition that a physician may only use the device after receiving special training. For example, when the FDA approved a stair-climbing wheelchair, it required physicians to undergo special training before they could prescribe the chair for their patients. *See* <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00933.html>; *see also* <http://www.fda.gov/FDAC/departs/2001/601_upd.html> (noting that before implanting certain devices, physicians are required to receive special training).

Here, after reviewing Cytyc's PMA application and the underlying clinical data, FDA restricted the device to physicians only, but declined to impose any training, instructional, or tutorial requirements on physicians who seek to use the NovaSure device.[1] As a result, under the MDA, neither Cytyc nor any of its employees owe any duty to the patient to teach, instruct or tutor physicians on the use of the device. By alleging that Cytyc has such a duty and that it negligently breached that duty, plaintiff is seeking to impose on Cytyc a requirement that is in addition to the ones imposed on it by the FDA. As such, the putative requirement and corresponding duty are preempted by FDCA § 521(a) and the Court's holding in *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).[2] Plaintiff concedes this much.[3] Plaintiff's Response at 7.

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[1] *See* <http://www.fda.gov/cdrh/pdf/P010013.html> setting out the FDA's conditions of approval for NovaSure and other FDA approved documents.

[2] Alternatively, the claims are impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Here too, plaintiff concedes that if plaintiff's claims sought to enforce compliance with FDA regulations, then *Buckman* would preempt those claims. Plaintiff's Response at 9. Plaintiff asserts, however, that her claims are different; she is challenging the relationship between the defendants and their agent rather than the relationship

3. The Learned Intermediary Doctrine Bars Liability

Even if the plaintiff's negligence claim were somehow not preempted and were deemed appropriate even though there is no claim that Cytyc or its representative did anything that adversely affected the safety or effectiveness of the NovaSure device, the negligence claim would still be barred under Virginia's Learned Intermediary Doctrine. The doctrine holds that a device manufacturer owes a duty to the physician to provide appropriate labeling for its medical devices, but that duty does not extend to the patient. *See Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (applying Virginia law in a medical device case). The doctrine is triggered unless there is a showing or an allegation that the physician was not acting independently or as an intervening agent between the patient and the physician. Here, there is no such allegation in the complaint and therefore, the doctrine applies precluding the formation of a duty between Cytyc and the patient. Absent such a duty, the plaintiff's negligence claim evaporates.

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between defendants and the FDA. *Id.* at 10. The distinction plaintiff draws is more semantic than real since the relationship between the defendants and their alleged agent (the corporate representative) is governed by the FDA procedures.

[3] That concession was required under *Riegel*. *See O'Neal v. SmithKline Beecham Corp.*, 2008 WL 275782 (E.D. Cal 2008) (denying reconsideration of the dismissal of common law claims against drug manufacturer on preemption grounds). *See also BIC Pen Corp. v. Carter*, 2008 WL 1765550 (Tex. 2008) (holding that federal law preempts design defect claims against a product approved by the Consumer Safety Product Commission).

CONCLUSION

For the foregoing reasons, Cytyc respectfully requests that the Court grant it Motion to Dismiss as to all claims.

Respectfully Submitted,

/s/ Geoffrey J. Greeves
Geoffrey J. Greeves (Va. Bar #41499)
Robert P. Charrow (Admitted *Pro Hac Vice*)
David P. Callet (Admitted *Pro Hac Vice*)
GREENBERG TRAURIG, LLP
2101 L Street N.W.
Suite 1000
Washington, DC 20037
Tel. (202) 331-3100
Fax. (202) 331-3101
charrowr@gtlaw.com

Attorneys for Defendants Cytyc Corporation et al.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 30th day of April, 2008, a true copy of the foregoing was electronically filed with the Clerk of this court using the CM/ECF System which will send notification of such filing to the following:

William W. Brock, IV, Esq.
Gentry Locke Rakes & Moore LLP
800 Sun Trust Plaza
P.O. Box 40013
Roanoke, VA 24022-0013
Telephone: 540-983-9300
Fax: 540-983-9400
Email: Wirt_Brock@gentrylocke.com

S.D. Roberts Moore, Esq.
Gentry Locke Rakes & Moore LLP
800 Sun Trust Plaza
P.O. Box 40013
Roanoke, VA 24022-0013
Telephone: 540-983-9300
Fax: 540-983-9400
Email: Roberts_Moore@gentrylocke.com

Frank N. Cowan, Esq.
CowanGates PC
1930 Huguenot Road
P.O. Box 35655
Richmond, VA 23235-0655
Telephone: 804-320-9100
800-948-7160
Fax: 804-330-3140
Email: fcowan@cowangates.com

Counsel for Plaintiff

By: **/s/Geoffrey J. Greeves**
Geoffrey J. Greeves (VSB No. 41499)